



Global Overview of the Threat

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**A global problem
that constitutes a
significant public
health threat
to many nations !!!**



UNODC

United Nations Office on Drugs and Crime

**The challenge of
new psychoactive substances**

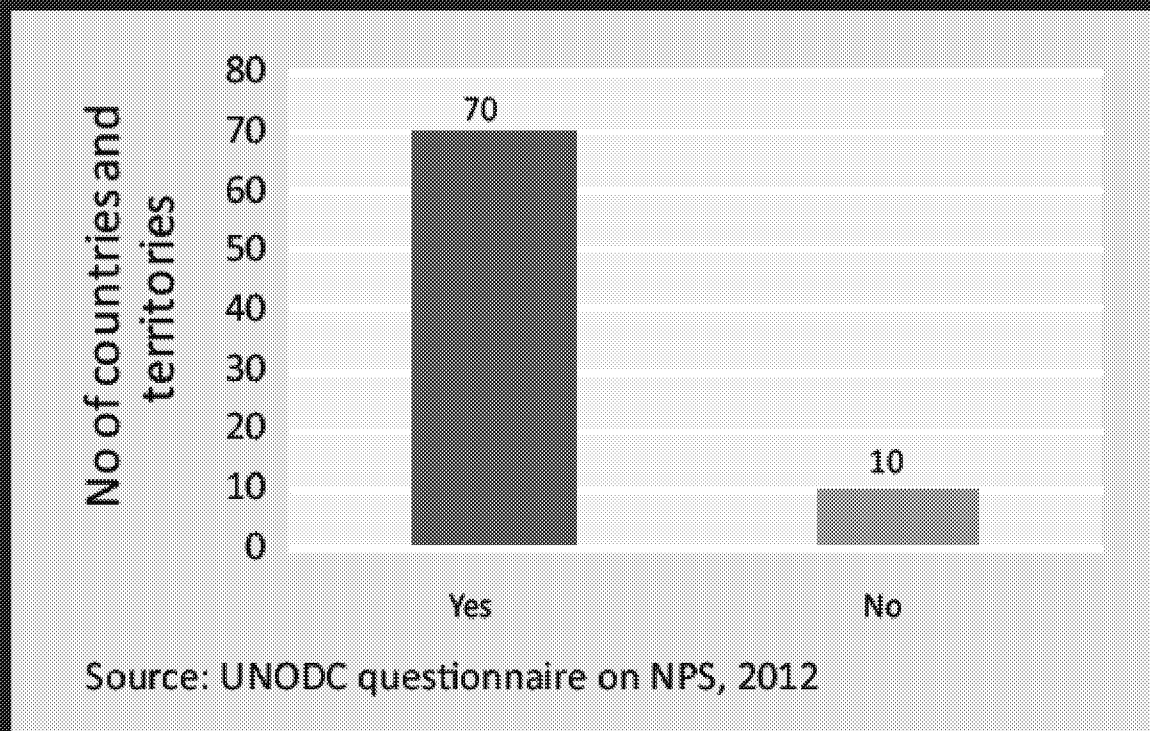
Global SMART Programme

2013

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Global Synthetic Drug Use



Of the nations surveyed, 87 % (70 out of 80) indicate that NPS are available in their respective drug markets.

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Global Synthetic Drug Use

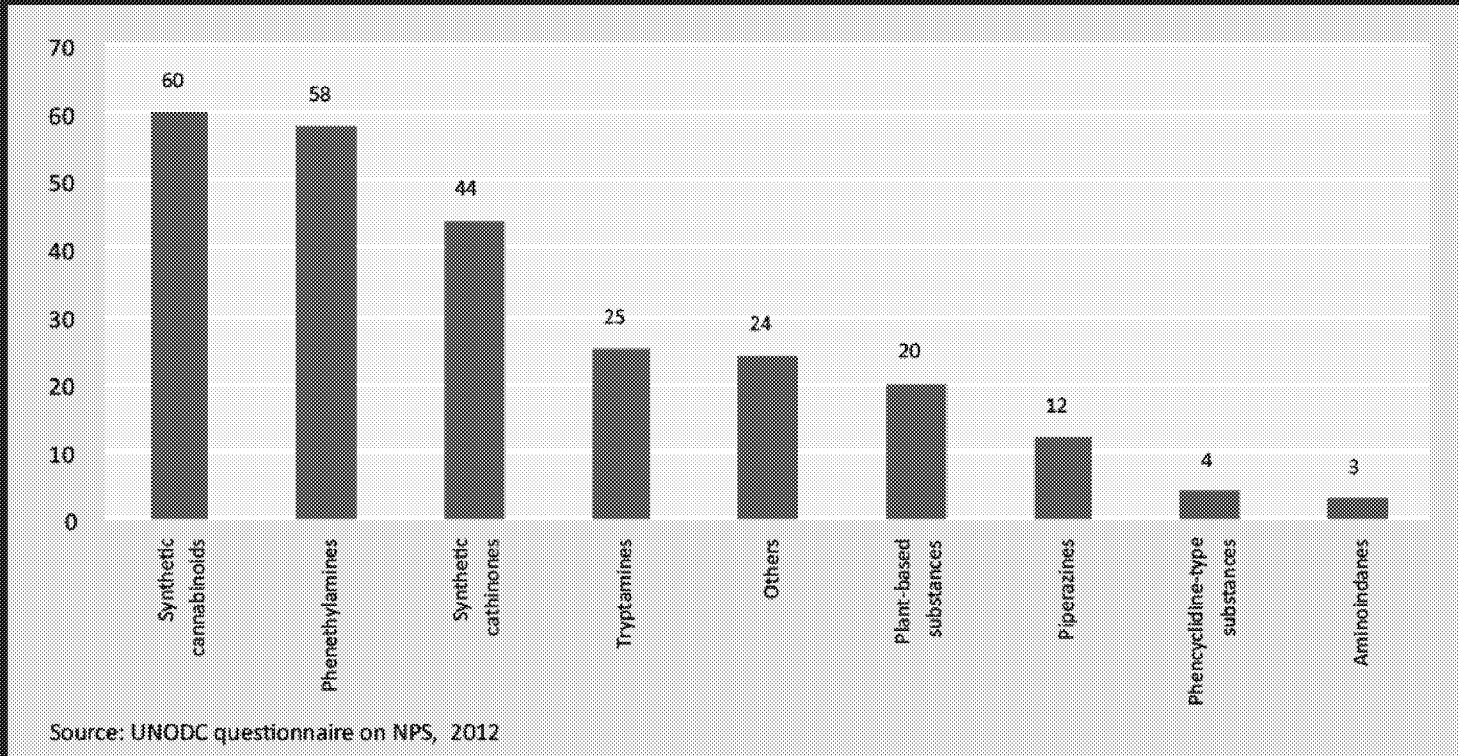


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Case 3:17-cv-01362 Document 1149-10 Filed 10/30/20 Page 5 of 38 PageID #: 40110

Number of NPS on Global Markets (2009-2012)

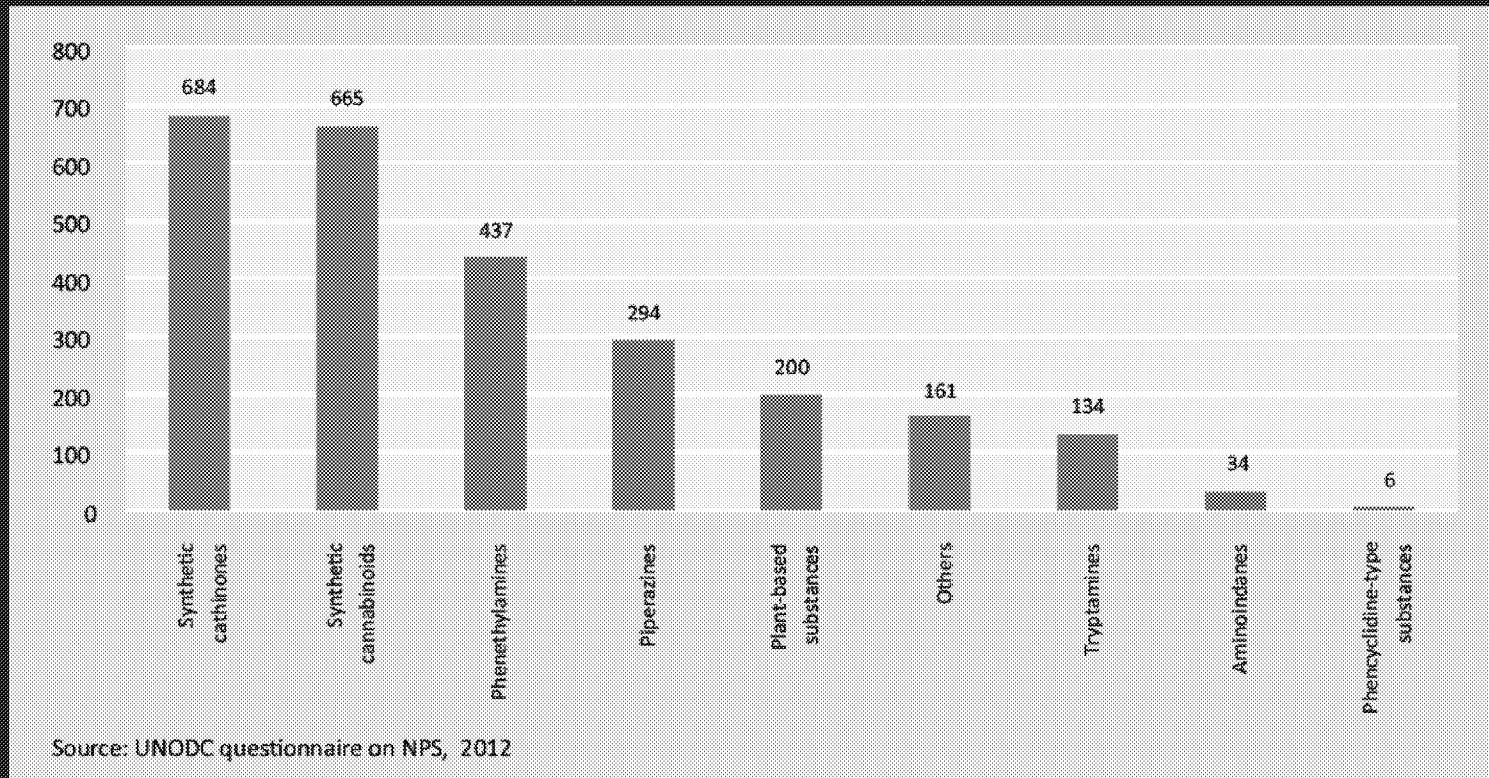


A total of 251 NPS (including ketamine) were reported to UNODC by 40 countries and territories up to 2012.

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Number of NPS in Global Markets (2009-2012)



At the global level, most reports pertaining to NPS concern synthetic cathinones, with 684 reports, followed by synthetic cannabinoids with 665 reports

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Trend of NPS Seizures (2009 – 2012)

NPS group	2009	2010	2011	2012
Synthetic cannabinoids	↑	↑	↑	↑
Synthetic cathinones	↑	↑	↑	↔
Ketamine	↔	↔	↔	↔
Phenethylamines	↔	↑	↔	↔
Piperazines	↑	↔	↔	↓
Plant-based substances	↑	↑	↑	↔
Miscellaneous	-	↑	↑	↑

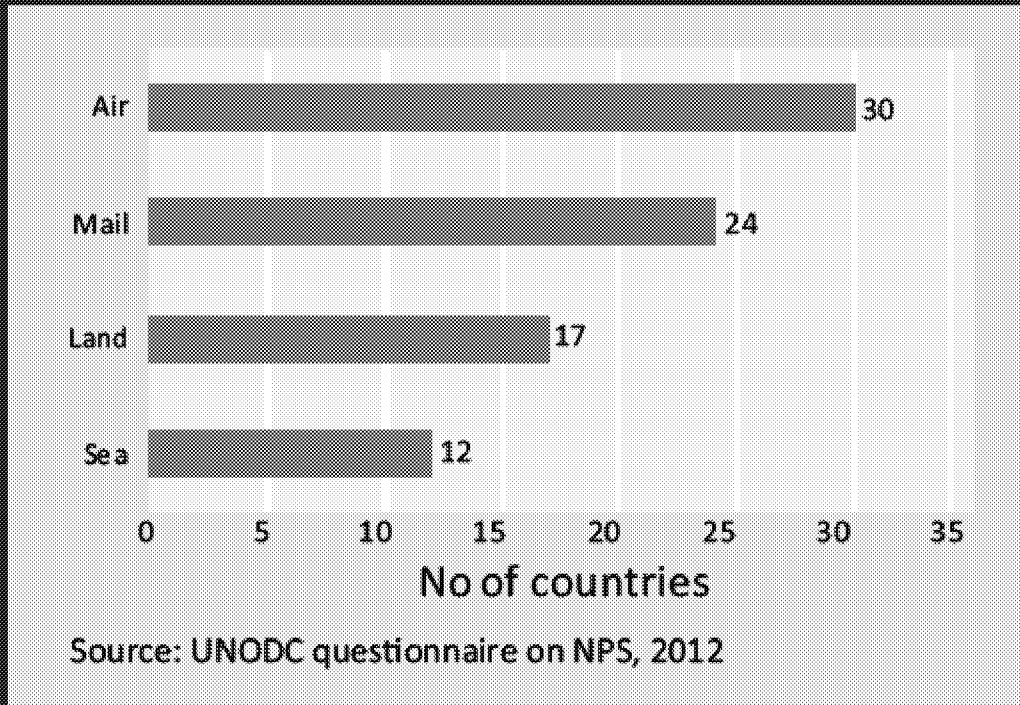
↑ = Increasing, ↓ = Decreasing, ↔ = Stable, - unknown
Source: UNODC questionnaire on NPS, 2012 and ARQ

Trends for the seven NPS groups fluctuate.
Seizures of ketamine, phenethylamines and piperazines stable
Rising trends for synthetic cannabinoids, cathinones,
and plant-based substances

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NPS Trafficking Modes



Source: UNODC questionnaire on NPS, 2012

The mode of trafficking named by most respondents was trafficking by air (30 countries) followed by trafficking by mail (24 countries), without any regional variations.

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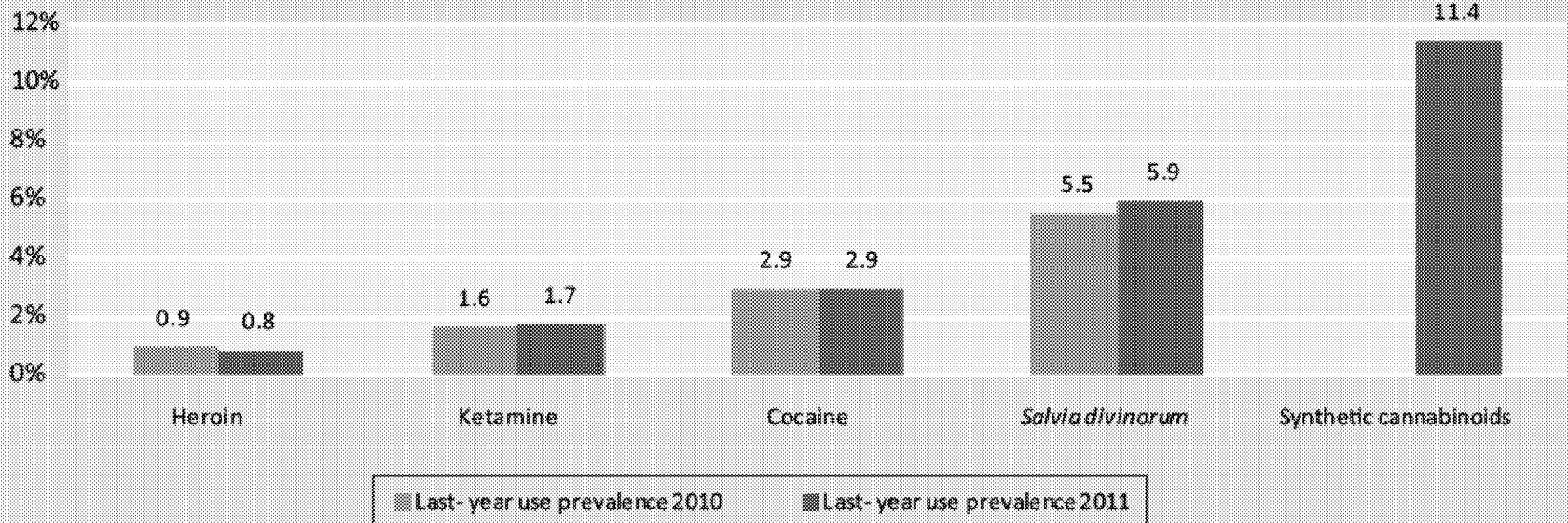


U. S. Overview & Experience

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United States: Prevalence of Drug and NPS Use Among 12th Graders (2010 – 2011)



Source: data from the MTF Survey 2010-2011

Base: 12th graders %

Question on synthetic cannabinoids was introduced in 2011 for the first time

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Identified Synthetic Compounds in the U.S.

As of October 15, 2013, the U.S. has encountered:

- 99 synthetic cannabinoids
- 52 synthetic cathinones
- 89 other compounds (2C compounds, tryptamines, piperazines, etc.)

240 Compounds and Counting !!!!

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‘Spice’ makers alter recipes to sidestep state laws banning synthetic marijuana



Rob Ostermaier/Daily Press - Police show what they suspect is “spice,” confiscated during a raid on Outer Edge Gifts in Hampton, Va., on April 5.

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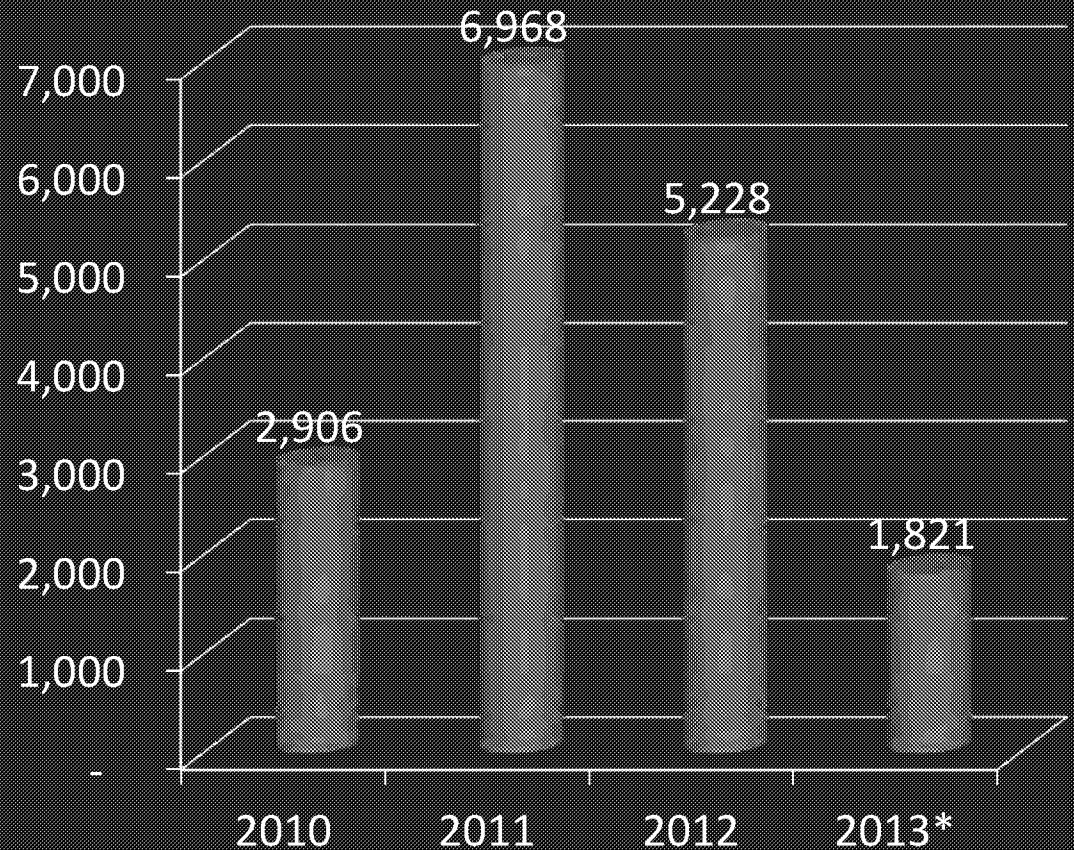


Calls to U.S. Poison Control Centers

American Association of
Poison Control Centers
(AAPCC) Reporting

Calls to poison control
centers for exposures to
synthetic marijuana
(synthetic cannabinoids)

Synthetic Cannabinoids



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*As of August 31, 2013

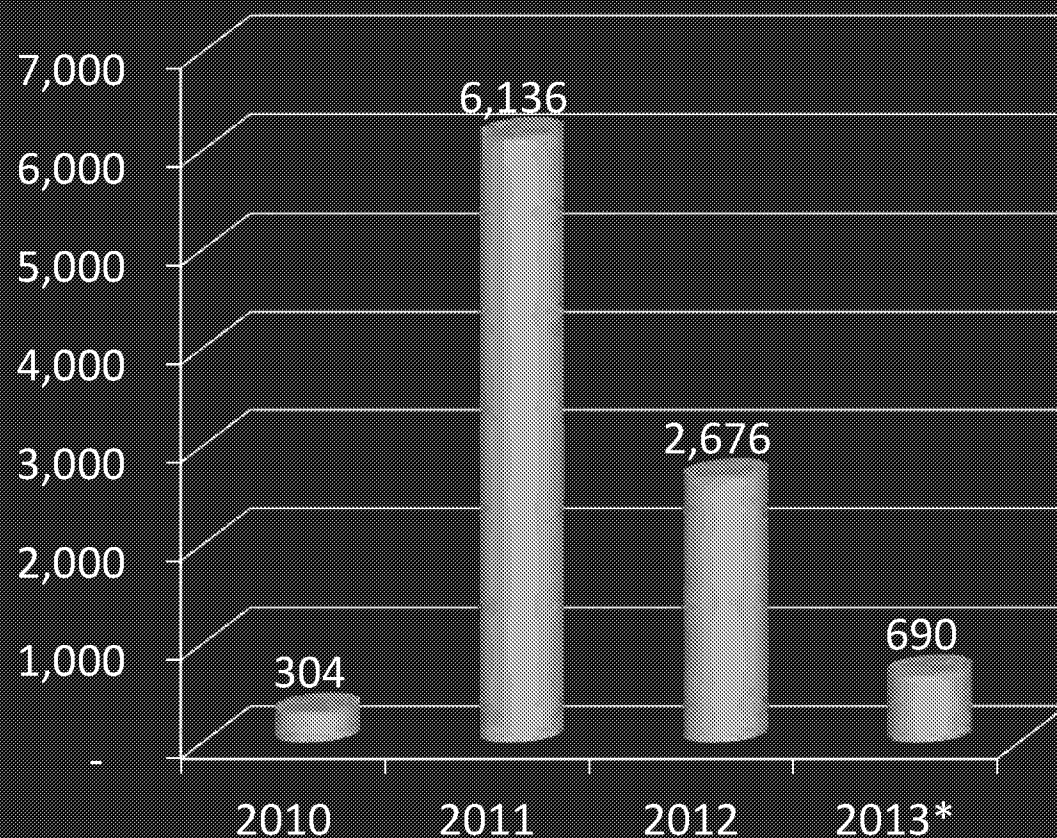


Calls to U.S. Poison Control Centers

American Association of
Poison Control Centers
(AAPCC) Reporting

Calls to poison control
centers for exposures to
bath salts (synthetic
cathinones)

Synthetic Cathinones



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*As of August 31, 2013



Public Safety Concerns

- Driving Under the Influence of Drugs (DUIDs) with fatalities
- Suicides
- Homicide-Suicide
- Overdoses
 - Emergency Department visits
 - First Responders
- Drugs abused to evade drug screens
 - 30-35% of juveniles in drug court tested positive
 - Individuals subjected to routine drug screens
 - Probationer / parolees

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Warning!

Bangor Daily News

Bangor man on bath salts carried assault-style rifle through city, police say

By Nok-Noi Ricker, BDN Staff
Posted July 27, 2011, at 12:50 p.m.

the man's ex-girlfriend told police at about 7:30 p.m. Tuesday that he had used bath salts and was "stating that people were coming out of his mattress,"

lice,
bath

When Bangor police searched the man's apartment on Walter Street Tuesday night, they found the assault-style rifle and two pieces wrapped in plastic. Police searched the apartment on Walter Street a few minutes after 7 p.m. Tuesday. "When questioned, the man stated that the two pieces wrapped in plastic were .223 [caliber] ammunition. He did not tell police where the gun was,"

A local agent of the FBI interviewed the suspect.

The man was released Tuesday evening. The case is being reviewed for possible state and-or federal charges, Edwards said.



Edwards, went into the man's

Edwards found the man on Buck

Edwards did in fact find an M4 rifle in the apartment and 18 separate rounds of

Edwards said, adding, "we did confiscate

Edwards, along with Bangor police,



First Responder Encounters

- **Altered mental status presents as severe panic attacks, agitation, paranoia, hallucinations, and violent behavior (e.g., self-mutilation, suicide attempts, and homicidal activity). (Spiller *et al.*, *Clinical Toxicology* 2011)**
 - climbing into the attic of the home with a gun to kill demons that were hiding
 - breaking all the windows in a house and wandering barefoot through the broken glass
 - jumping out of a window to flee from non-existent pursuers; requiring electrical shock (Taser) and eight responders to initially subdue the patient
 - repeatedly firing guns out of the house windows at “strangers” who were not there
- **Bath salts use tied to three Bangor (Maine) deaths. (Richter, *JEMS* 2012)**
- **Bath salt abuse: new designer drug keeps EMS crews busy nationwide. (Nevin, *JEMS* 2011)**



First Responders (Cont.)

Drug Endangered Children:

- Leaving a 7-year-old daughter in the middle of a highway because she had demons (Spiller *et al.*, *Clinical Toxicology* 2011)
- A drug-intoxicated couple hallucinated they were being burglarized, began shooting into walls. Officers found weapons in every room, and a paranoid parent huddled inside the bathroom with two young children and a loaded .357 Magnum (Macher, *American Jails* 2011)
- Northeast PA, couple charged with multiple offenses for stabbing at “90-people living in their walls” with 5-year old present (*Times-Leader.com*, Mar 21, 2011)



Synthetic Drug “Manufacturing Facility”?



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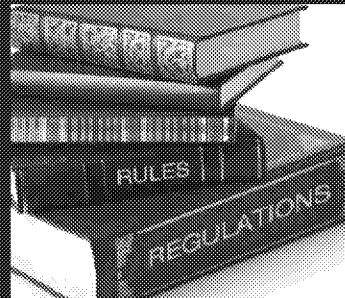


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Ready to Ship...






Control Efforts: Using all the “Tools” Available



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Synthetic Drugs: U.S. State Controls

- 
- A light gray silhouette of the United States map, including the contiguous states, Alaska, and Hawaii, is positioned in the background. Overlaid on the central part of the map is a bulleted list of state-level entities.
- Legislation
 - Department of Health
 - Pharmacy Board
 - Consumer Affairs Dept.



U.S. Federal Scheduling & Rescheduling Procedures

Placement of a substance into one of the U.S. Federal Controlled Substance Act (CSA) schedules can be done by statute or through the administrative process.

- **Statute:** Congress may designate a substance a controlled substance or reschedule a drug within the scheduling hierarchy by passing legislation. This, by far, is the easiest method in which to add, remove or transfer a substance between schedules.

- **Administrative Process:** The Attorney General, by rule, (using his administrative authority) to add, remove or transfer a substance between schedules. **The legal definition of control, "...means to add a drug or other substance, or immediate precursor, to a schedule...whether by transfer of another schedule or otherwise". 21 USC 802(5)**

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Federal Temporary Scheduling

- Because of the lack of effective legislative controls to combat the synthetic problem early on, federally we looked to temporary scheduling as a solution
- Requires an AG finding (delegated down to DEA) that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety
- ...and the substance is not listed in any other schedule in Section 21 USC 812 or no exemption or approval is in effect under the FDCA

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Federal Temporary Scheduling

(Comprehensive Crime Control Act of 1984)

As set forth under 21 U.S.C 811(h), three factors (4, 5 &6) under the CSA (21 U.S.C. 811(c)) are to be considered in the evaluation

1. Its actual or relative potential for abuse
2. Scientific evidence of its pharmacological effects
3. The state of current scientific knowledge regarding the substance
4. Its history and current pattern of abuse
5. The scope, duration, and significance of abuse
6. What, if any, risk there is to the public health
7. Its psychic or physiological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled

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Federal Temporary Scheduling Process

- DEA collects information from law enforcement and public health officials regarding encounters and evaluates this information relative to the three factors required for temporary scheduling.
- Once sufficient information has been collected, a letter is transmitted from DEA to the U.S. Department of Health & Human Services (DHHS) to communicate intention to temporary schedule [and to verify no active new drug applications (NDAs) or investigations drug applications (INDs) for the proposed substances filed].

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Federal Temporary Scheduling Process

- DEA letter of intent to DHHS, solicits a comment to control these substances within 30 days. Based on the DHHS response, a “Notice of Intent” can be published in the U.S. Federal Register with a “Final Order” published at minimum 30-days after the “Notice of Intent”.
- As there is no “comment period” provided for temporary scheduling, civil and criminal sanctions applicable to the manufacture, possession, importation, and exportation are effective upon publication of the “Final Order”.

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Issued in Washington, D.C. on April 2, 2013.
 Gary A. Nords,
 Manager, Airspace Policy and ATC,
 Federal Aviation Admin.
 FAA Doc. 2013-08166 Filed 4-3-13; 4453207
 25,190; 2702; 456,55.2

Exhibit No. DEA-973

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, Mailing Address: 200 Massachusetts Drive, Springfield, Virginia 22152, telephone: (703) 297-7165.

Background:
Section 201 of the CIA (28 U.S.C. 811) provides the Attorney General with

[illegible][illegible]

A subcommittee meeting the necessary requirements for temporary scheduling (25 M.S.A. §§11-113) may only be placed in Schedule I. Subcommittees in Schedule II are those that have a high potential for abuse but currently accepted medical use in treatment in the United States (M.S.A. and a lack of accepted safety for use under medical supervision. 32 M.S.A. §§12-111. Available data and information for 192-144, M.S.A. and AKBs indicate that these substances, cannabinoids, have a high potential for abuse, are not currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision.

While synthetic compounds have been developed over the last 50 years for numerous purposes in investigating the mammalian system, an essential tool for the study of the mammalian system is the use of a specific, sensitive, and reliable method for the detection of a specific compound. The use of a specific, sensitive, and reliable method for the detection of a specific compound is essential for the study of the mammalian system. The use of a specific, sensitive, and reliable method for the detection of a specific compound is essential for the study of the mammalian system.

DEA/DOJ ODE page 1 of 34 Apr. 12, 2013



U.S. Federal Temporary Scheduling Actions Relative to Synthetic Drugs

To date, 8 Synthetic Cannabinoids, 3 Synthetic Cathinone, and 3 Phenethylamine Compounds have been controlled or in the process of being controlled

- 5 Cannabinoid Compounds (March 2011 Final Order)
- 3 Cathinone Compounds (October 2011 Final Order)
- 3 Cannabinoid Compounds (May 2013 Final Order)
- 3 Phenethylamine Compounds [i.e. “NBOMe” products (October 2013 Notice of Intent)]

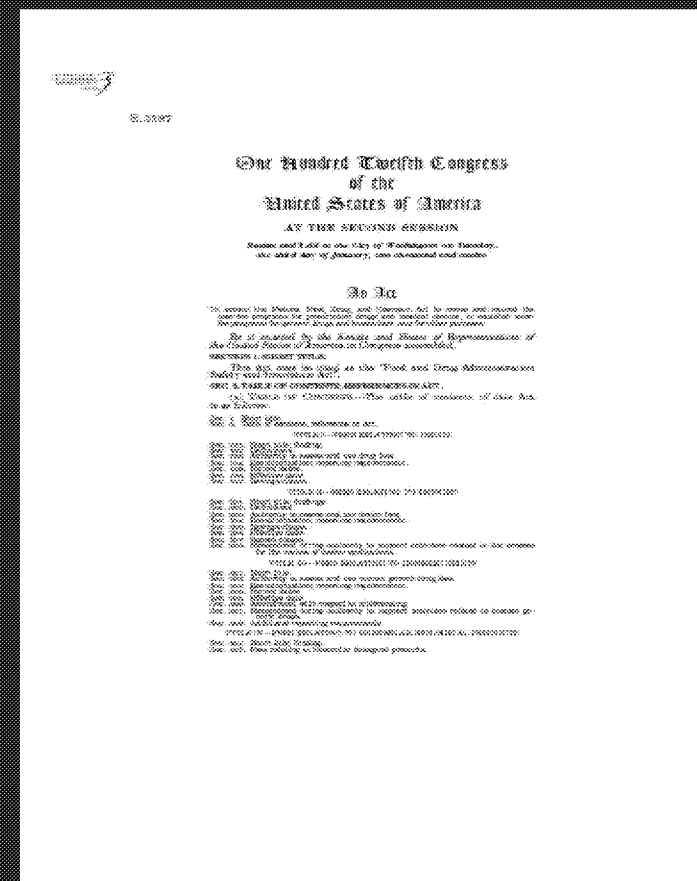
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U.S. Synthetic Drug Abuse Prevention Act of 2012

On July 9, 2012, the President signed the Synthetic Drug Abuse Prevention Act of 2012 (Public Law 112-144)

➤ The law controlled 26 compounds into schedule I



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U.S. Synthetic Drug Abuse Prevention Act of 2012

- Defined the term “Cannabimimetic Agent” [any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist].
- Extends the maximum time that DEA may temporarily control a substance.
- Initial time period for temporary scheduling increased from 12 to 24 months / Extension period increased from 6 months to 12 months.

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U.S. Synthetic Drug Abuse and Prevention Act 2012

Cannabinoids

- | | |
|--------------------------------|-------------|
| 1) AM2201 | 8) JWH-200 |
| 2) AM694 | 9) JWH-019 |
| 3) CP-47,497 | 10) JWH-250 |
| 4) CP-47,497 –
C8 homologue | 11) JWH-122 |
| 5) JWH-018 | 12) JWH-203 |
| 6) JWH-073 | 13) JWH-398 |
| 7) JWH-081 | 14) SR-19 |
| | 15) SR-18 |

Cathinones

- 1) Mephedrone
- 2) MDPV

Phenethylamines

- 1) 2C-E
- 2) 2C-D
- 3) 2C-C
- 4) 2C-I
- 5) 2C-T-2
- 6) 2C-T-4
- 7) 2C-H
- 8) 2C-N
- 9) 2C-P



The Way Forward on the International Front

- Working to identify major foreign based sources
- Working to sensitize partner nations regarding the threat and the need for international controls
- Continue to work bilaterally and with international partners to look at coordinating global outreach and cooperation

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The Way Forward on the International Front / CND Resolutions

Enhancing International Cooperation in the Identification & Reporting of NPS (E/CN.7/2013/L.2/ March 2013)

United Nations

E/CN.7/2013/L.2/Rev.1



Economic and Social Council

Distr.: Limited
14 March 2013

Original: English

Commission on Narcotic Drugs

Fifty-ninth session

Vienna, 11-15 March 2013

Agenda item 4

Implementation of the international drug control treaties

Australia, Croatia, El Salvador, Finland, Hungary, Israel, Japan, Mexico,
New Zealand, Peru, Russian Federation, Thailand, Turkey, Ukraine,
United Kingdom of Great Britain and Northern Ireland and
United States of America: revised draft resolution

**Enhancing international cooperation in the identification and
reporting of new psychoactive substances***The Commission on Narcotic Drugs,*

Recalling its resolution 48/1 of 11 March 2005, on promoting the sharing of
information on emerging trends in the abuse of and trafficking in substances not
controlled under the international drug control conventions,

Recalling also its resolution 53/11 of 12 March 2010, on promoting the
sharing of information on the potential abuse of and trafficking in synthetic
cannabinoid receptor agonists,

Recalling further its resolution 53/13 of 12 March 2010 on the use of
"poppers" as an emerging trend in drug abuse in some regions,

Recalling its resolution 55/1 of 16 March 2012, on promoting international
cooperation in responding to the challenges posed by new psychoactive substances,

Reiterating its concern at the number of potentially dangerous new
psychoactive substances that continue to be marketed as legal alternatives to
internationally controlled drugs, circumventing existing controls,

Concerned that emerging new psychoactive substances may have effects
similar to those of internationally controlled drugs and may pose risks to public
health and safety, and noting the need for additional data on the effects of these
substances to be collected and shared,

V.13-51852 (E)



Please recycle

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The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution:

- ***Encourages*** nations to take a comprehensive and coordinated approach to the detection, analysis, and identification of NPS
- ***Urges*** nations to share with one another information on the identification of NPS using, where appropriate, existing national and regional early warning systems and networks
- ***Urges*** nations to include information on the potential adverse impacts and risks to public health and safety of new psychoactive substances through prevention & awareness to counter public perceptions on NPS

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The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution (Continued):

- *Encourages* nations, and relevant international institutions, to share and exchange ideas, best practices, and experiences regarding new laws, regulations and restrictions, to attack the NPS issue
- *Urges* the UNODC to continue to develop a voluntary electronic portal for national forensic and/or drug testing laboratories to enable timely and comprehensive sharing of information on NPS (an early warning system)

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Thank You

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